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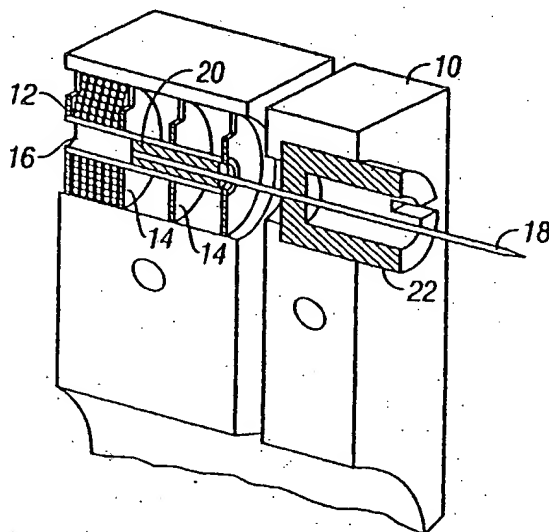
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(54) Title: METHOD AND APPARATUS FOR CONNECTING CONDUCTIVE MEDIA



(57) Abstract: A body fluid sampling device is provided. In one embodiment, the invention comprises a set of pins that obviate the need for leads from the disposable device. The pins may be integrated into the tissue penetrating device. The pins are inserted into the printed electrochemical electrodes and are reusable. The disposable chemistry is simplified in the process. The use of the simplified disposable in an integrated sampling device also creates a potential for miniaturization. In another embodiment, the device comprises a support structure. The device includes sensory material on a first side of said support structure and a conductor material on a second side of said support structure. A plurality of holes defined by the support structure may be used. The hole allows the conductor material to contact the sensory material. In yet

another embodiment, the invention teaches a design and method of providing conduction lines originating from a sensor on one side of the substrate and terminating in such a way that they are accessible from the reverse side.

WO 2005/065415 A2

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WO 2005/065415 A2



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METHOD AND APPARATUS FOR CONNECTING CONDUCTIVE MEDIA

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BACKGROUND OF THE INVENTION

Field of the Invention

The invention relates to the collection of body fluid and to the connection of devices for reading analyte measurements of the body fluid.

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Description of Related Art

Treatment of diabetes requires frequent monitoring of levels of blood glucose.

This is traditionally done in a series of steps involving the preparation of a lancing device, preparation of a glucose meter, lancing a finger, transporting the resulting blood drop to the meter, and finally obtaining a blood glucose reading.

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Lancing devices are known in the medical health-care products industry for piercing the skin to produce blood for analysis. Biochemical analysis of blood samples is a diagnostic tool for determining clinical information. Many point-of-care tests are performed using capillary whole blood, the most common being monitoring diabetic blood glucose level. Other uses for this method include the analysis of oxygen and coagulation based on Prothrombin time measurement. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

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Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. Typically, the device is pre-cocked or the user cocks the device. The device is held against the skin and mechanically triggers the ballistic launch of the lancet. The forward movement and depth of skin penetration of the lancet is determined by a mechanical stop and/or dampening, as well as a spring or cam to retract the lancet. Spontaneous blood droplet generation is dependent on reaching the blood capillaries and venuoles, which yield the blood sample.

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The devices used for measuring glucose levels sometimes use electrochemical sensors. Creating the electrical couplings in a cost-effective and efficient manner for these ever shrinking devices can be challenging. In the current practice for making connections between an electrochemical sensor and a meter, the electrical conduction lines are printed on the same side of the substrate as the sensors. During the measurement process the substrate end where the connection pad are printed is then inserted into a connector embedded into the meter. Sometimes, however, the sensor substrate may optionally be integrated with a lancing cartridge in such a way that the sensor side of the substrate is not directly accessible for connecting to the meter. The design may desired that providing a continuous electrical conduction line from one side of the substrate to the other make the connections to the meter. Accordingly, in some devices, what is required is a simple method of enabling the connectivity on the reverse side.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide an improved, integrated fluid sampling device. To improve device integration, devices and methods for connecting sensor regions to contact pad regions may be provided. One of the problems involves getting electrical contact with the leads connected to electrodes coupled to the sensor regions. At least some of these and other objectives described herein will be met by embodiments of the present invention.

The printing of the leads to the electrodes becomes complex when other structures competing for space and the drive toward miniaturizing integrated sampling. One embodiment of the present invention removes the leads from the disposable device and integrates the sensor leads into the lancing device. The integrated lancing system contains pins which are pierced into the printed electrochemical electrodes.

In one embodiment, the present invention comprises of a set of pins on the lancing device that connect to the electrodes on the disposable device. These pins provide a connection for the sensor analysis circuitry.

In another embodiment, a body fluid sampling system is provided for measuring analyte levels in the body fluid. The system comprises a housing having a transparent window; a cartridge in the housing; a plurality of penetrating member in the cartridge; a

plurality of analyte detecting members mounted on the cartridge; a plurality of pins mounted on the housing, the pins and cartridge movable relative to one another, the pins movable relative to the housing to pierce the analyte detecting members on the cartridge to create a good electrical contact.

5 The present invention may also provide solutions such as an improved, integrated fluid sampling device. To improve device integration, devices and methods for connecting sensor regions to contact pad regions may be provided. One of the problems that this invention solves is the ability to deposit sensory material on the topside of a support structure for exposure to bodily fluids via a lancing, sampling, and capturing
10 structure or device. At least some of these and other objectives described herein will be met by embodiments of the present invention.

 In one embodiment of the present invention, methods and devices are provide to allow the conduction of sensory device signals to pass through a support and insulated plate structure. The insulated plate maybe fabricated from polymer materials, known to
15 those practicing the arts, of which the conductive material is a deposited carbon based compound. The deposition of such a thick film is generated thru the art known as "screen printing" or "thick film lithography". The thick film is annealed as to remove any liquid carrier and to conductive as well as structure sound to support the deposition of sensory electrochemical material and devices. The thickness of such conductive material is
20 typically in the range of 1 to 10 "mils" or 100's of "microns".

 In one embodiment, the present invention proposes the use of either screen-printing or electroplating (Galvanic) to produce the conductive media between two different layers. It teaches a method of making the vias for the "Dark Tunnel" or via hole concept by using multiple miniature vias all acting together as a single feed through line.
25 The use of multiple vias guarantees interlayer continuity by diminishing the probability of discontinuities. The distribution of the lateral via contact will be in even clusters as to minimize the lateral topology. This topology may also be planarized as to prevent sensor surface discontinuities. The advantages in such a method is the ability to "double up" the used area to be used for both sensors and vias. This is a common practice in the IC
30 technology known in the arts as "buried contacts". In this art, the active MOS transistor sources or drains are integrated in with the vias of the upper metal layers and includes the

direct metal contacts to polysilicon and doped channel junctions. Thus in a similar practice we are combining the active sensor material along with the conductor contacts.

The invention relates to the conduction of sensory signals on one side of an insulated polymer layer and its sensory signal conduction through and upon another side of the same polymer layer.

This invention pertains to the use of both electrical active conductors and electrochemical sensory components. When space and the necessity to utilize both sides of a substrate becomes a dominating issue, it becomes necessary to integrate the interlayer interconnects along with the sensory structures. One method is to incorporate the sensors directly on the same foot print as the interlayer interconnects, thus conserving substrate surface area or space.

The present invention may also involve solutions for providing conduction lines originating from a sensor on one side of the substrate and terminating in such a way that they are accessible from the reverse side. At least some of these and other objectives described herein will be met by embodiments of the present invention.

In one embodiment, the invention relates to the design of conduction layers for permit connection of the electrode on the backside of the sensor substrate. The technical field relates to the process of depositing conduction lines on a glucose sensor substrate in such a way that conduction pathway for the signal originates from the sensors on one side of the substrate and continues on the reverse side of the substrate. This permits contacting the sensors with sample on one side and make electrical connections for interrogating the sensors on the reverse side of the substrate material.

In one embodiment of present invention, a device is provided for body fluid sampling device. The device comprises a support structure; a sensory material on a first side of the support structure; and at least one conductor pin positioned to pierce into the sensory material to create an electrical connection; wherein the sensory material is sized to prevent the conductor pins from piercing entirely through the material. The device may have a radial cartridge, wherein the support structure is coupled to the radial cartridge.

In yet another embodiment of the present invention, a method is provided for use on a patient. The method comprises providing a sampling device having a cartridge in a housing, a plurality of penetrating member in the cartridge; a plurality of analyte

detecting members mounted on the cartridge; and a plurality of pins mounted on the housing; moving the pins and cartridge relative to one another; piercing the analyte detecting members on the cartridge with the pins movable relative to the housing to create a good electrical contact; and reading analyte measurements of fluid in contact with the analyte detecting members. The analyte detecting members may be made of a material sufficiently pliable to be penetrated by the pins.

In a still further embodiment of the present invention, a body fluid sampling system is provided for measuring analyte levels in the body fluid. The system comprises a housing; a cartridge in the housing; a plurality of penetrating member in the cartridge; a plurality of analyte detecting members mounted on the cartridge; and a plurality of pins mounted on the housing, the pins and cartridge movable relative to one another, the pins movable relative to the housing to pierce the analyte detecting members on the cartridge to create a good electrical contact. A wicking member may be coupled to each of the analyte detecting member and positioned to extend over at least a portion of a penetrating member exit chamber on the cartridge.

The cartridge may include a plurality of openings allowing the pins to engage an underside of the analyte detecting member. The pins may be mounted on a movable chassis that moves to engage the cartridge in a first position, and disengages from the cartridge in a second position. The pins may be mounted on the housing and may repeatedly pierce the cartridge to make the electrical connection for each glucose measuring event. The pins may be insulated on a lower portion to prevent cross-talk. The analyte detecting member may be about 700 microns thick. The analyte detecting member may be about 500 microns thick. The analyte detecting member may be about 300 microns thick.

In yet another embodiment of the present invention, a device is provided for body fluid sampling. The device comprises a support structure; a sensory material on a first side of the support structure; a conductor material on a second side of the support structure; and at least one via hole defined by the support structure, the via hole allowing the conductor material to contact the sensory material, the via hole sized to allow some material to reach the otherside of the substrate. The device may include a plurality of via holes in the support structure, wherein each is sized to allow some material to reach the otherside of the substrate. The device may include a plurality of via holes in the support

structure arranged in a configuration selected from one of the following: circular, oval, or rectangular.

In yet another embodiment of the present invention, a method is provided that comprises the following: providing a support structure; forming a plurality of miniature
5 via holes in the support structure; depositing sensory material on one side of the support structure; and depositing conductor material on another side of the support structure, the conductor material and sensory material in contact with one another. The method may involve coupling the support structure to one side of a radial cartridge. The method may
10 involve coupling the support structure to one side of a radial cartridge and applying a sterility barrier around the entire cartridge. The method may involve coupling the support structure to one side of a radial cartridge and mounting a plurality of penetrating members on the cartridge.

In yet another embodiment of the present invention, a device is provided for use with a metering device for measuring analyte levels. The device comprises a sensing
15 disc; a connector disc; a plurality of analyte detecting members mounted on the sensing disc; and a plurality of contact pads on the connector disc forming a lap joint with the sensing disc, wherein the analyte detecting members face upward and the contact pads of the connector disc face downward.

A further understanding of the nature and advantages of the invention will become
20 apparent by reference to the remaining portions of the specification and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates an embodiment of a controllable force driver in the form of a cylindrical electric penetrating member driver using a coiled solenoid-type configuration.

25 Figure 2A illustrates a displacement over time profile of a penetrating member driven by a harmonic spring/mass system.

Figure 2B illustrates the velocity over time profile of a penetrating member driver by a harmonic spring/mass system.

Figure 2C illustrates a displacement over time profile of an embodiment of a
30 controllable force driver.

Figure 2D illustrates a velocity over time profile of an embodiment of a controllable force driver.

Figure 3 is a diagrammatic view illustrating a controlled feed-back loop.

Figure 4 is a perspective view of a tissue penetration device having features of the invention.

Figure 5 is an elevation view in partial longitudinal section of the tissue penetration device of Figure 4.

Figure 6A shows one embodiment of a device which may use the present invention.

Figure 6B shows one embodiment of a cartridge according to the present invention.

Figure 7A is a perspective view of one embodiment of the present invention with conductor which pierce into at least one electrode.

Figure 7B is a side view of one embodiment where wicking member and capillary structure may be used with the electrodes of the present invention.

Figure 8 is a side view of a conductor and electrode according to the present invention.

Figures 9A and 9B show perspective view of one embodiment of the present invention.

Figures 10A and 10B show conductor configurations.

Figures 11A and 11B shows close-up views of conductors according to the present invention.

Figures 12 and 13 are side views of embodiments using via holes.

Figure 14 shows a perspective view of one substrate with a particular via hole configuration.

Figure 15 shows cross-sectional view of one embodiment of the present invention.

Figure 16 shows a perspective view of one substrate with another via hole configuration.

Figure 17 is cross-sectional view of a connection using an overlap joint.

Figure 18 is perspective view of two discs according to the present invention.

Figures 19A through 19C show various top down views of the discs according to the present invention.

Figures 20 and 21 are enlarged views of one embodiment of contact pads and electrical leads according to the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include mixtures of materials, reference to "a chamber" may include multiple chambers, and the like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

"Optional" or "optionally" means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

The present invention may be used with a variety of different penetrating member drivers. It is contemplated that these penetrating member drivers may be spring based, solenoid based, magnetic driver based, nanomuscle based, or based on any other mechanism useful in moving a penetrating member along a path into tissue. It should be noted that the present invention is not limited by the type of driver used with the penetrating member feed mechanism. One suitable penetrating member driver for use with the present invention is shown in Figure 1. This is an embodiment of a solenoid type electromagnetic driver that is capable of driving an iron core or slug mounted to the penetrating member assembly using a direct current (DC) power supply. The electromagnetic driver includes a driver coil pack that is divided into three separate coils along the path of the penetrating member, two end coils and a middle coil. Direct current is alternated to the coils to advance and retract the penetrating member. Although the driver coil pack is shown with three coils, any suitable number of coils may be used, for example, 4, 5, 6, 7 or more coils may optionally be used.

Referring to the embodiment of Figure 1, the stationary iron housing 10 may contain the driver coil pack with a first coil 12 flanked by iron spacers 14 which concentrate the magnetic flux at the inner diameter creating magnetic poles. The inner insulating housing 16 isolates the penetrating member 18 and iron core 20 from the coils and provides a smooth, low friction guide surface. The penetrating member guide 22 further centers the penetrating member 18 and iron core 20. The penetrating member 18 is protracted and retracted by alternating the current between the first coil 12, the middle coil, and the third coil to attract the iron core 20. Reversing the coil sequence and attracting the core and penetrating member back into the housing retracts the penetrating member. The penetrating member guide 22 also serves as a stop for the iron core 20 mounted to the penetrating member 18.

As discussed above, tissue penetration devices which employ spring or cam driving methods have a symmetrical or nearly symmetrical actuation displacement and velocity profiles on the advancement and retraction of the penetrating member as shown in Figures 2 and 3. In most of the available penetrating member devices, once the launch is initiated, the stored energy determines the velocity profile until the energy is dissipated. Controlling impact, retraction velocity, and dwell time of the penetrating member within the tissue can be useful in order to achieve a high success rate while accommodating variations in skin properties and minimize pain. Advantages can be achieved by taking into account of the fact that tissue dwell time is related to the amount of skin deformation as the penetrating member tries to puncture the surface of the skin and variance in skin deformation from patient to patient based on skin hydration.

In this embodiment, the ability to control velocity and depth of penetration may be achieved by use of a controllable force driver where feedback is an integral part of driver control. Such drivers can control either metal or polymeric penetrating members or any other type of tissue penetration element. The dynamic control of such a driver is illustrated in Figure 2C which illustrates an embodiment of a controlled displacement profile and Figure 2D which illustrates an embodiment of a the controlled velocity profile. These are compared to Figures 2A and 2B, which illustrate embodiments of displacement and velocity profiles, respectively, of a harmonic spring/mass powered driver. Reduced pain can be achieved by using impact velocities of greater than about 2 m/s entry of a tissue penetrating element, such as a penetrating member, into tissue.

Other suitable embodiments of the penetrating member driver are described in commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395, (Attorney Docket No. 38187-2551) filed April 19, 2002 and previously incorporated herein.

Figure 3 illustrates the operation of a feedback loop using a processor 60. The processor 60 stores profiles 62 in non-volatile memory. A user inputs information 64 about the desired circumstances or parameters for a lancing event. The processor 60 selects a driver profile 62 from a set of alternative driver profiles that have been preprogrammed in the processor 60 based on typical or desired tissue penetration device performance determined through testing at the factory or as programmed in by the operator. The processor 60 may optionally customize by either scaling or modifying the profile based on additional user input information 64. Once the processor has chosen and customized the profile, the processor 60 is ready to modulate the power from the power supply 66 to the penetrating member driver 68 through an amplifier 70. The processor 60 may measure the location of the penetrating member 72 using a position sensing mechanism 74 through an analog to digital converter 76 linear encoder or other such transducer. Examples of position sensing mechanisms have been described in the embodiments above and may be found in the specification for commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395, (Attorney Docket No. 38187-2551) filed April 19, 2002 and previously incorporated herein. The processor 60 calculates the movement of the penetrating member by comparing the actual profile of the penetrating member to the predetermined profile. The processor 60 modulates the power to the penetrating member driver 68 through a signal generator 78, which may control the amplifier 70 so that the actual velocity profile of the penetrating member does not exceed the predetermined profile by more than a preset error limit. The error limit is the accuracy in the control of the penetrating member.

After the lancing event, the processor 60 can allow the user to rank the results of the lancing event. The processor 60 stores these results and constructs a database 80 for the individual user. Using the database 79, the processor 60 calculates the profile traits such as degree of painlessness, success rate, and blood volume for various profiles 62 depending on user input information 64 to optimize the profile to the individual user for subsequent lancing cycles. These profile traits depend on the characteristic phases of penetrating member advancement and retraction. The processor 60 uses these

calculations to optimize profiles 62 for each user. In addition to user input information 64, an internal clock allows storage in the database 79 of information such as the time of day to generate a time stamp for the lancing event and the time between lancing events to anticipate the user's diurnal needs. The database stores information and statistics for each user and each profile that particular user uses.

In addition to varying the profiles, the processor 60 can be used to calculate the appropriate penetrating member diameter and geometry suitable to realize the blood volume required by the user. For example, if the user requires about 1-5 microliter volume of blood, the processor 60 may optionally select a 200 micron diameter penetrating member to achieve these results. For each class of penetrating member, both diameter and penetrating member tip geometry, is stored in the processor 60 to correspond with upper and lower limits of attainable blood volume based on the predetermined displacement and velocity profiles.

The lancing device is capable of prompting the user for information at the beginning and the end of the lancing event to more adequately suit the user. The goal is to either change to a different profile or modify an existing profile. Once the profile is set, the force driving the penetrating member is varied during advancement and retraction to follow the profile. The method of lancing using the lancing device comprises selecting a profile, lancing according to the selected profile, determining lancing profile traits for each characteristic phase of the lancing cycle, and optimizing profile traits for subsequent lancing events.

Figure 4 illustrates an embodiment of a tissue penetration device, more specifically, a lancing device 80 that includes a controllable driver 179 coupled to a tissue penetration element. The lancing device 80 has a proximal end 81 and a distal end 82. At the distal end 82 is the tissue penetration element in the form of a penetrating member 83, which is coupled to an elongate coupler shaft 84 by a drive coupler 85. The elongate coupler shaft 84 has a proximal end 86 and a distal end 87. A driver coil pack 88 is disposed about the elongate coupler shaft 84 proximal of the penetrating member 83. A position sensor 91 is disposed about a proximal portion 92 of the elongate coupler shaft 84 and an electrical conductor 94 electrically couples a processor 93 to the position sensor 91. The elongate coupler shaft 84 driven by the driver coil pack 88 controlled by the

position sensor 91 and processor 93 form the controllable driver, specifically, a controllable electromagnetic driver.

Referring to Figure 5, the lancing device 80 can be seen in more detail, in partial longitudinal section. The penetrating member 83 has a proximal end 95 and a distal end 96 with a sharpened point at the distal end 96 of the penetrating member 83 and a drive head 98 disposed at the proximal end 95 of the penetrating member 83. A penetrating member shaft 201 is disposed between the drive head 98 and the sharpened point 97. The penetrating member shaft 201 may optionally be comprised of stainless steel, or any other suitable material or alloy and have a transverse dimension of about 0.1 to about 0.4 mm. The penetrating member shaft may optionally have a length of about 3 mm to about 50 mm, specifically, about 15 mm to about 20 mm. The drive head 98 of the penetrating member 83 is an enlarged portion having a transverse dimension greater than a transverse dimension of the penetrating member shaft 201 distal of the drive head 98. This configuration allows the drive head 98 to be mechanically captured by the drive coupler 85. The drive head 98 may have a transverse dimension of about 0.5 to about 2 mm.

A magnetic member 102 is secured to the elongate coupler shaft 84 proximal of the drive coupler 85 on a distal portion 203 of the elongate coupler shaft 84. The magnetic member 102 is a substantially cylindrical piece of magnetic material having an axial lumen 204 extending the length of the magnetic member 102. The magnetic member 102 has an outer transverse dimension that allows the magnetic member 102 to slide easily within an axial lumen 105 of a low friction, possibly lubricious, polymer guide tube 105' disposed within the driver coil pack 88. The magnetic member 102 may have an outer transverse dimension of about 1.0 to about 5.0 mm, specifically, about 2.3 to about 2.5 mm. The magnetic member 102 may have a length of about 3.0 to about 5.0 mm, specifically, about 4.7 to about 4.9 mm. The magnetic member 102 can be made from a variety of magnetic materials including ferrous metals such as ferrous steel, iron, ferrite, or the like. The magnetic member 102 may be secured to the distal portion 203 of the elongate coupler shaft 84 by a variety of methods including adhesive or epoxy bonding, welding, crimping or any other suitable method.

Proximal of the magnetic member 102, an optical encoder flag 206 is secured to the elongate coupler shaft 84. The optical encoder flag 206 is configured to move within a slot 107 in the position sensor 91. The slot 107 of the position sensor 91 is formed

between a first body portion 108 and a second body portion 109 of the position sensor 91. The slot 107 may have separation width of about 1.5 to about 2.0 mm. The optical encoder flag 206 can have a length of about 14 to about 18 mm, a width of about 3 to about 5 mm and a thickness of about 0.04 to about 0.06 mm.

5 The optical encoder flag 206 interacts with various optical beams generated by LEDs disposed on or in the position sensor body portions 108 and 109 in a predetermined manner. The interaction of the optical beams generated by the LEDs of the position sensor 91 generates a signal that indicates the longitudinal position of the optical flag 206 relative to the position sensor 91 with a substantially high degree of resolution. The
10 resolution of the position sensor 91 may be about 200 to about 400 cycles per inch, specifically, about 350 to about 370 cycles per inch. The position sensor 91 may have a speed response time (position/time resolution) of 0 to about 120,000 Hz, where one dark and light stripe of the flag constitutes one Hertz, or cycle per second. The position of the optical encoder flag 206 relative to the magnetic member 102, driver coil pack 88 and
15 position sensor 91 is such that the optical encoder 91 can provide precise positional information about the penetrating member 83 over the entire length of the penetrating member's power stroke.

An optical encoder that is suitable for the position sensor 91 is a linear optical incremental encoder, model HEDS 9200, manufactured by Agilent Technologies. The
20 model HEDS 9200 may have a length of about 20 to about 30 mm, a width of about 8 to about 12 mm, and a height of about 9 to about 11 mm. Although the position sensor 91 illustrated is a linear optical incremental encoder, other suitable position sensor embodiments could be used, provided they possess the requisite positional resolution and time response. The HEDS 9200 is a two channel device where the channels are 90
25 degrees out of phase with each other. This results in a resolution of four times the basic cycle of the flag. These quadrature outputs make it possible for the processor to determine the direction of penetrating member travel. Other suitable position sensors include capacitive encoders, analog reflective sensors, such as the reflective position sensor discussed above, and the like.

30 A coupler shaft guide 111 is disposed towards the proximal end 81 of the lancing device 80. The guide 111 has a guide lumen 112 disposed in the guide 111 to slidably accept the proximal portion 92 of the elongate coupler shaft 84. The guide 111 keeps the

elongate coupler shaft 84 centered horizontally and vertically in the slot 102 of the optical encoder 91.

The driver coil pack 88, position sensor 91 and coupler shaft guide 111 are all secured to a base 113. The base 113 is longitudinally coextensive with the driver coil pack 88, position sensor 91 and coupler shaft guide 111. The base 113 can take the form of a rectangular piece of metal or polymer, or may be a more elaborate housing with recesses, which are configured to accept the various components of the lancing device 80.

As discussed above, the magnetic member 102 is configured to slide within an axial lumen 105 of the driver coil pack 88. The driver coil pack 88 includes a most distal first coil 114, a second coil 115, which is axially disposed between the first coil 114 and a third coil 116, and a proximal-most fourth coil 117. Each of the first coil 114, second coil 115, third coil 116 and fourth coil 117 has an axial lumen. The axial lumens of the first through fourth coils are configured to be coaxial with the axial lumens of the other coils and together form the axial lumen 105 of the driver coil pack 88 as a whole. Axially adjacent each of the coils 114-117 is a magnetic disc or washer 118 that augments completion of the magnetic circuit of the coils 114-117 during a lancing cycle of the device 80. The magnetic washers 118 of the embodiment of Figure 5 are made of ferrous steel but could be made of any other suitable magnetic material, such as iron or ferrite. The outer shell 89 of the driver coil pack 88 is also made of iron or steel to complete the magnetic path around the coils and between the washers 118. The magnetic washers 118 have an outer diameter commensurate with an outer diameter of the driver coil pack 88 of about 4.0 to about 8.0 mm. The magnetic washers 118 have an axial thickness of about 0.05, to about 0.4 mm, specifically, about 0.15 to about 0.25 mm.

Wrapping or winding an elongate electrical conductor 121 about an axial lumen until a sufficient number of windings have been achieved forms the coils 114-117. The elongate electrical conductor 121 is generally an insulated solid copper wire with a small outer transverse dimension of about 0.06 mm to about 0.88 mm, specifically, about 0.3 mm to about 0.5 mm. In one embodiment, 32 gauge copper wire is used for the coils 114-117. The number of windings for each of the coils 114-117 of the driver pack 88 may vary with the size of the coil, but for some embodiments each coil 114-117 may have about 30 to about 80 turns, specifically, about 50 to about 60 turns. Each coil 114-117 can have an axial length of about 1.0 to about 3.0 mm, specifically, about 1.8 to about 2.0

mm. Each coil 114-117 can have an outer transverse dimension or diameter of about 4.0, to about 2.0 mm, specifically, about 9.0 to about 12.0 mm. The axial lumen 105 can have a transverse dimension of about 1.0 to about 3.0 mm.

It may be advantageous in some driver coil 88 embodiments to replace one or
5 more of the coils with permanent magnets, which produce a magnetic field similar to that of the coils when the coils are activated. In particular, it may be desirable in some embodiments to replace the second coil 115, the third coil 116 or both with permanent magnets. In addition, it may be advantageous to position a permanent magnet at or near the proximal end of the coil driver pack in order to provide fixed magnet zeroing function
10 for the magnetic member (Adams magnetic Products 23A0002 flexible magnet material (800) 747-7543).

Referring now to Figures 6A and 6B, yet another embodiment of the present invention will now be described. It should be understood that this embodiment may be adapted for use with devices described in commonly assigned copending U.S. Patent
15 Applications Ser. No. 10/323,624 (Attorney Docket No. 38187-2608) filed December 18, 2002. Figure 6A shows a device that may use a cartridge as shown in Figure 6B. Figure 6B shows a radial cartridge 220. The cartridge 220 may include a sterility barrier 232 and a substrate 250 having a plurality of analyte detecting members 226. In this embodiment, the cartridge 220 is designed so that blood will enter the fluid chamber 228 and be held
20 there for analysis.

Figure 6B shows the radial cartridge 220 may be used with a lancing device 230. The radial cartridge 220 may be sealed with a sterility barrier 232 and be coupled to analyte detecting members mounted on a substrate 234. A suitable device is described in commonly assigned, copending U.S. Patent Application No. 10/429,196 (Attorney
25 Docket No. 38187-2662) fully incorporated herein by reference for all purposes. It should be understood that in some embodiments, the layer 234 may be removed and the bottom layer of the cartridge 220 sealed. Instead, a ring 252 with a plurality of analyte detecting members 254 (such as those shown in Figures 7 to 21) may optionally be in a ring configuration around the penetrating member cartridge 220. This orients one analyte
30 detecting member 254 for each penetrating member in cartridge 220. Some embodiments may optionally have portions of the ring 254 fold underneath the cartridge 220 in an L-configuration when viewed from a side cross-sectional (as shown in Figure 7B).

Figure 7A shows one embodiment of a much simpler way to bridge between the electrode material 300 and the analysis circuit that simplifies the disposable involves the use of pins that are located in the tissue penetrating device. The chemistry may still be deposited on a film and bonded together with the plastic portion of the disposable (See Figures 9A and 9B).

Figure 7B shows that in one embodiment of the present invention, the pierceable electrode 300 may optionally be adapted for use with a wicking member 311 and capillary structure 313 to bring fluid to the electrode 300. The wicking member 311 is may optionally be intersected by the penetrating member 317. The wicking member 315 may have a hole to allow the penetrating member to pass without having the member cut the wicking member. In one possible embodiment, two of the pins 310 are in electrical communication as indicated by phantom line 319.

Referring now to Figure 8, in one embodiment with an advancing mechanism, the pins 310 will lift out of the prior use module, and then pierce through the film 320 into the electrode 300. The active surface 330 that is exposed to blood is not altered. In one embodiment, the pin control is integrated with the mechanical slider advance mechanism disclosed in U.S. Patent Applications Ser. No. 10/323,624 (Attorney Docket No. 38187-2608) filed December 18, 2002. Prior to the piercing event, the pins 310 may be aligned axially with the footprint of their corresponding electrodes. It should be understood that the pins 310 may optionally be configured or positioned as desired to match the configuration or layout of the electrodes 300. In integrated sampling, the tissue penetrating assembly will already be precisely aligned—the “x and y” alignment is already controlled. The depth, or “z” axis alignment of the pins is a two-part process. The insertion, or “biting” of the pins into the electrode material should imbed properly into the electrode. The retraction, or removal of the pins must be a sufficient length to allow the advance mechanism to move the next module of lancet and sensor into place. The electrode composition should be thick enough and soft enough for the pins to embed in the chemistry without altering the way that the electrodes directly perform their function. When the pins 310 are removed, the electrode 300 or film 320 should not adhere to the pin.

Figures 9A and 9B show that the film 320 and the mold of the cartridge 220 may optionally be formed separately and then combined to form a cartridge with analyte

detecting members. In some embodiments, the pins are stationary and the cartridge 220 move upward and downward to engage the electrodes 300 to the pins 310. In other embodiments, the pins may optionally be in the same horizontal plane as the electrodes 300 and engage them laterally (either the pins move or the cartridge slides to engage the pins). In most embodiments, the electrodes 300 may optionally be of a thickness (and width) that prevents the pins 310 from puncturing through and contacting blood. It should be understood that the single slot cartridge shown in Figure 9B may be extended to have a plurality of these slots arranged in a radial configuration to define a radial disc such as that shown in Figure 6B.

Figures 10A and 10B show the electrodes 300 and conductor pins may be in a variety of configurations. Figure 10A shows a 3 pin and 3 electrode configuration. Figure 10B shows a 4 pin and 4 electrode configuration. Figure 11 shows the pin may have a variety of shapes including polygonal, round, cylindrical, pyramid, combinations of the above, and other shapes to allow good contact with the electrodes 300. As seen in Figure 11A, a lower portion 340 of the pin 310 may be insulated (as compared to the pin 310 in Figure 11B) to reduce cross-talk.

Referring now Figure 12, another aspect of the present invention will now be described. The technical field relates to several key technologies. One technology is the use of screen-printing technology in the formulation of contact vias for two layer laminate structures. The galvanic plating technology has been developed to implement the PC board and flex circuitry industry for "plating" up interconnect structures. Lastly, the use of both screen printing and electro plating technologies have been used very heavily in the design of hybrid circuitry for RF electronics and electrosensors. MEMS technology and the LIGA process has also placed a heavy emphasis on the use of electroplating as a method of creating high aspect ratio structures.

Figures 12 and 13 show two side views of embodiments of the device 400 according to the present invention. Figure 12 depicts one embodiment comprising a generic polymer dielectric thick film serving as an insulating support structure 412. The support structure 412 may be, but is not limited to, Mylar, Tyvek, polymer or plastic film insulators. On the top side of the insulating structure 412 are electrochemical sensory material 414 and on the bottom side of the insulating structure 412 are electrical signal conductors 416 for the sensors. The materials 414 and 416 are coupled together through a

via hole structure 418. The material 414 may include, but is not limited to, carbon ink, silver ink, or other electrically conductive material.

Figure 13 depicts an application of the device 410. The support structure 412 is being used to provide isolation and sensory material isolation from the bottom environment. In one embodiment, the top would be sealed or isolated from the environment to maintain a sterile condition prior to use, while the bottom would be exposed to the environment and allow the instrumentation access to the electrical sensory signals from the sensory material. Although this embodiment is shown with three sensors, it should be understood that different numbers of sensing members or sensory material 414 (greater or fewer) may be used. Some embodiments may use one via hole structure 418 to join multiple sensing members 414 to a single pad 416, multiple pads 416 to a single sensing member 414, multiple sensing members 414 to multiple pads 416, or any other combination of pads to sensing members.

This invention is intended to allow the conduction of sensory device signals to pass through a support and insulated plate structure 412. The insulated plate 412 may be fabricated from polymer materials, known to those practicing the arts, of which the conductive material is a deposited carbon based compound. By way of example and not limitation, the deposition of such a thick film forming the plate 412 is generated through the art known as "screen printing" or "thick film lithography". In one embodiment, the thick film is annealed as to remove any liquid carrier and to conductive as well as structure sound to support the deposition of sensory electrochemical material and devices. The thickness of such conductive material is typically in the range of 1 to 10 "mils" or 100's of "microns". The problem that this invention solves is the ability to deposit sensory material on the topside of the film for exposure to bodily fluids via a lancing, sampling, and capturing structure or device. The invention allows the electrical signals from the sensory material to be conducted and transported to the instrumentation electronics on the backside of the device such that the electrical conductors are not exposed to the bodily fluids. Also the topside of the film containing the sensory material adjacent to the lancing and sample capturing structures may be sterilized or cleaned and stored until it becomes necessary to be utilized.

The electrical via 418 through the structural dielectric polymer may take various shapes and geometries as to provide structural support for the thick film conductive layer.

As a nonlimiting example, the via 418 may be circular, square, triangular, rectangular, polygonal, oval, or the like. Such patterns used for structural means are known to those practicing the arts of thick film depositions. The density and viscosity of the conductive film both cured and uncured is able to provide proper signal conductivity and sensory material structural support.

The present connectors and any embodiments disclosed herein may optionally be adapted for use with a radial cartridge such as that shown in commonly assigned, co-pending U.S. Patent Application Ser. No. 10/429,196 (Attorney Docket No. 38187-2662) filed May 1, 2003, fully incorporated herein by reference for all purposes.

Referring now to another embodiment of the present invention, Figure 14 shows that the contact pad may optionally be formed directly under the analyte detecting member. This invention pertains to the use of both electrical active conductors and electrochemical sensory components. When space and the necessity to utilize both sides of a substrate becomes a dominating issue, it becomes necessary to integrate the interlayer interconnects along with the sensory structures. One method is to incorporate the sensors directly on the same foot print as the interlayer interconnects, thus conserving substrate surface area or space.

In one embodiment, this method may optionally use a screen printing or galvanic process to create electrical feed throughs. This application has analyte detecting member on one side and conductors on the other. The area 420 beneath where the electrode will be formed may be perforated by a plurality of holes 422 to allow some material to seep to the other side. The thick film oozes through the backside. The item is then baked. A similar pattern or other shaped pattern is then screen printed on the other side to make the contacts. Increasing the number of holes creates parallel paths which drops the resistance. It also increases the reliability since all that is required is a small subset of holes to connect. In some embodiments, the structure may optionally have at least 5, 10, 15, 20, 30, 40, 50, or 100 or more via holes per area 420.

Figure 15 shows that this embodiment of the present invention may position a plurality of holes in the substrate area directly under the analyte detecting member. Figure 15 shows material 430 on a top side and a material 440 on a bottom side. The remaining layers of the analyte detecting member may optionally be applied to the top or bottom layers. The holes 422 may be in a regular distribution or in some pattern. Figure

- 16 shows a circular pattern of miniature via holes 422 may be used. During the manufacturing of the analyte detecting member, a thick film paste such as but not limited to a carbon paste or silver chloride paste, is used to form a conductive layer. A portion of this layer will seep into the plurality of holes. In one embodiment, this material is partially baked to cure it. The entire substrate is flipped over and another layer of material is added on the area on this side of the substrate that corresponds to the location of the analyte detecting member. This creates the electrical connection. This creates a connection to the other side of the substrate and it does not use up extra space on the cartridge since the contact pad is formed substantially, directly underneath the layer. This method of manufacturing may involve plating up and use of a galvanic process. It should be understood that these via holes 422 may be formed on a cartridge as shown in Figure 6B in a manner so that each penetrating member is associated with at least one via hole sensing device. The entire cartridge may then be sealed with a sterility barrier 232 as shown in Figure 6B.
- 15 With any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge may be in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member.
- 20 The penetrating member may have a diameter and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. The sensory material 14 may be deposited into the via holes 18. The conductor material may also be deposited into the via holes. The via holes may be formed by a variety of methods including micro drilling, laser drilling, plasma etching, or the like. The embodiments herein are adapted for use with lancing devices
- 25 described in U.S. Patent Applications Ser. No. 10/127,395 (Attorney Docket No. 38187-2551US) and U.S. Patent Applications Ser. No. 10/323,622 (Attorney Docket No. 38187-2606US). Relevant techniques include the use of electrochemical sensors and its fabrication upon either Kapton-polyimide substrates or disposable plastic substrates such
- 30 as glucose test strips. Relevant techniques also include the recent developments in biosensors fabricated upon either silicon, glass, or molded plastic surfaces with the intent of integrating sample capture and measurements in a small surface profile.

Referring now to Figure 17, one embodiment of another aspect of the present invention will now be described. A plurality of analyte detecting members 510 are located at one portion of the substrate. The members 510 in this embodiment are connected to a conductive layer 520 to provided electrical signals from the analyte
5 detecting members 510 to a meter device. However, to provide connection to a connector pin, commutator pad, or other connector that faces upward, the present invention uses a lap joint to provide a downward facing surface 30 that the meter can connect to.

Figure 17 describes a design of a lap joint for connecting two conduction layers in such a way that one layer connects to the electrodes and the other connects to pins for
10 reading out the output form the electrodes. The lap joint method and design permits reading the sensors for the reverse side of the insulating substrate on which the electrodes are deposited. The invention comprises of method and design for providing means to connect electrodes or other such devices located on an insulating substrate to pin structures located on the opposite side.

15 In one embodiment, the conduction lines emanating from the electrodes on the insulating substrate are joined to conduction lines on another insulating substrate such that they make face-to-face contact at the conducting surfaces. The two laminates can be held together by adhesives positioned between the conduction lines or other similar means. The net result of the lap joint is that the conduction lines on the second substrate
20 allow connection to electrical circuitry from the other side of the electrode surface.

Figure 18 shows that overlap joint may actually be formed by two discs. The sensing disc 540 contains the detecting members 510 and the connector disc 550 forms the lap joint and provides the surface for contact to the metering device.

Figure 19A shows a top down view of the sensing disc 540. Figure 19B shows a
25 top down view of the connector disc 550. In one embodiment, where the discs 540 and 550 are combined, the contact pads of the disc 550 (Figure 19C) are facing one side, while the members 510 on the disc 540 are facing the other side (i.e. one is facing up, the other is facing down). Of course, it should be understood that other type of electrodes and a variety testing techniques may also be adapted for use with the disc 540 and 550.

30 As seen in Figure 20, a connector disc 550 provides a plurality of connector pads 560 to facilitate electrical connection with connectors on the metering portion of the device. Although not limited to the following, each connector pad 560 may have a size of

at least 1 mm² to facilitate sliding contact with the metering device as seen in Figure 21. The disc 550 also has smaller pads 570 for matching up with pads 580 on the analyte detecting member disc 540.

Referring now to Figure 19C, it can be seen that the discs 540 and 550 can be combined together. In one embodiment as seen in Figure 18, the connector disc 550 is located between a substrate such as, but not limited to, a disc 600 and the analyte detecting member disc 540. Although not limited to the following, in some embodiments, the thickness of the connector disc may be less than approximately 50 μ m. In one embodiment, the dimensions of the connector disc 550 in one embodiment has a 25 mm inner diameter and a 46 mm outer diameter. The dimensions for various pads 570, electrodes 560, and related structure are shown in Figure 21 for one embodiment of the present invention. The measures are by way of example and are nonlimiting.

In another embodiment, another way for creating a contact between connector pads of the sensor-disc with the sliding contacts of the meter is to bring the connector pads directly on the disc 600. In this case, connector disc 550 may become optional. In this embodiment, the connector lines as well as the connector pads may be printed directly on the disc 600 by screen-printing. Although not limited to the following, the layout for the screens for printing the connector lines and the connector pads on the disc 600 may be the same as the layout for the screens for printing the connector lines and the connector pads on the connector-disc 550. For this printing procedure, a carrier (e.g., aluminum) having recesses for the discs 600 may be used. The value of the deep of the recess may be the same as the value of the thickness of the disc 600. Furthermore, the recesses in the carrier material may be constructed in such a way, that disc 600 will fix into the recess in a prescribed position. For performing a printing step directly on the disc 600, in this embodiment, there is little change to the disc 600. A very plane surface of the upper side (close to the sensor-disc) of the disc 600 may be used. In some embodiments, the rectangular recesses on the disc 600 are located at a position where the electrodes of the analyte detecting member disc 540 may be positioned.

It should be understood that the disc 540 in one embodiment provides enough analyte detecting members for 525 analyte measurement tests. It should be understood that any number of analyte detecting member may be provided on a disc such as but not limited to more than 17. Some may have no less than 20, 25, 30, 35, 40, 45, 50, 55, 60,

65, 70, 75, 80, 85, 90, 95, or 100 analyte detecting members. Some may have different analyte detecting members for measuring different analytes. In some embodiments, microfluidics and/or other methods as described herein may be used to draw fluid toward the analyte detecting members. Although not limited to the following, these microfluidics and other structures may be formed near the outer periphery of the disc.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention. For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during actuation (i.e. penetrating members do not pierce the penetrating member enclosure or protective foil during launch). With any of the above embodiments, the penetrating members may be a bare penetrating member during launch. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge maybe in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member. The penetrating member may have a diameters and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. The driver may use a through hole or other opening to engage a proximal end of a penetrating member to actuate the penetrating member along a path into and out of the tissue.

Any of the features described in this application or any reference disclosed herein may be adapted for use with any embodiment of the present invention. For example, the devices of the present invention may also be combined for use with injection penetrating members or needles as described in commonly assigned, copending U.S. Patent Application Ser. No. 10/127,395 (Attorney Docket No. 38187-2551) filed April 19, 2002. An analyte detecting member to detect the presence of foil may also be included in the lancing apparatus. For example, if a cavity has been used before, the foil or sterility barrier will be punched. The analyte detecting member can detect if the cavity is fresh or not based on the status of the barrier. It should be understood that in optional

embodiments, the sterility barrier may be designed to pierce a sterility barrier of thickness that does not dull a tip of the penetrating member. The lancing apparatus may also use improved drive mechanisms. For example, a solenoid force generator may be improved to try to increase the amount of force the solenoid can generate for a given current. A solenoid for use with the present invention may have five coils and in the present embodiment the slug is roughly the size of two coils. One change is to increase the thickness of the outer metal shell or windings surround the coils. By increasing the thickness, the flux will also be increased. The slug may be split; two smaller slugs may also be used and offset by $\frac{1}{2}$ of a coil pitch. This allows more slugs to be approaching a coil where it could be accelerated. This creates more events where a slug is approaching a coil, creating a more efficient system.

In another optional alternative embodiment, a gripper in the inner end of the protective cavity may hold the penetrating member during shipment and after use, eliminating the feature of using the foil, protective end, or other part to retain the used penetrating member. Some other advantages of the disclosed embodiments and features of additional embodiments include: same mechanism for transferring the used penetrating members to a storage area; a high number of penetrating members such as but not limited to 25, 50, 75, 100, 500, or more penetrating members may be put on a disk or cartridge; molded body about a lancet becomes unnecessary; manufacturing of multiple penetrating member devices is simplified through the use of cartridges; handling is possible of bare rods metal wires, without any additional structural features, to actuate them into tissue; maintaining extreme (better than 50 micron -lateral- and better than 20 micron vertical) precision in guiding; and storage system for new and used penetrating members, with individual cavities/slots is provided. The housing of the lancing device may also be sized to be ergonomically pleasing. In one embodiment, the device has a width of about 56 mm, a length of about 105 mm and a thickness of about 15 mm. Additionally, some embodiments of the present invention may be used with non-electrical force generators or drive mechanism. For example, the punch device and methods for releasing the penetrating members from sterile enclosures could be adapted for use with spring based launchers. The gripper using a frictional coupling may also be adapted for use with other drive technologies.

Still further optional features may be included with the present invention. For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during
5 actuation (i.e. penetrating members do not pierce the penetrating member enclosure or protective foil during launch). The penetrating members may be a bare penetrating member during launch. The same driver may be used for advancing and retraction of the penetrating member. Different analyte detecting members detecting different ranges of glucose concentration, different analytes, or the like may be combined for use with each
10 penetrating member. Non-potentiometric measurement techniques may also be used for analyte detection. For example, direct electron transfer of glucose oxidase molecules adsorbed onto carbon nanotube powder microelectrode may be used to measure glucose levels. In some embodiments, the analyte detecting members may be formed to flush with the cartridge so that a "well" is not formed. In some other embodiments, the analyte
15 detecting members may be formed to be substantially flush (within 200 microns or 100 microns) with the cartridge surfaces. In all methods, nanoscopic wire growth can be carried out via chemical vapor deposition (CVD) or other vapor deposition. In all of the embodiments of the invention, nanoscopic wires may be nanotubes. Any method useful for depositing a glucose oxidase or other analyte detection material on a nanowire or
20 nanotube may be used with the present invention. Additionally, for some embodiments, any of the cartridge shown above may be configured without any of the penetrating members, so that the cartridge is simply an analyte detecting device. Still further, the indexing of the cartridge may be such that adjacent cavities may not necessarily be used serially or sequentially. As a nonlimiting example, every second cavity may be used
25 sequentially, which means that the cartridge will go through two rotations before every or substantially all of the cavities are used. As another nonlimiting example, a cavity that is 3 cavities away, 4 cavities away, or N cavities away may be the next one used. This may allow for greater separation between cavities containing penetrating members that were just used and a fresh penetrating member to be used next. It should be understood that
30 nanowires may be used with any embodiment of the cartridges described herein. The size and diameters of the radial cartridges described herein may also vary and are not limited to the sizes shown herein. For any of the embodiments herein, the analyte detecting

members may be arranged in a ring configuration as shown in Figure 6B. The analyte detecting members may be arranged to be perpendicular to the exit path of the penetrating member for the cartridge. In some embodiments, the analyte detecting members may be arranged to be positioned along the exit path of the penetrating member for the cartridge, allowing the penetrating member to transect the detecting member.

In some embodiments, the penetrating members may be bent, curved, textured, shaped, or otherwise treated at a proximal end or area to facilitate handling by an actuator. The penetrating member may be configured to have a notch or groove to facilitate coupling to a gripper. The notch or groove may be formed along an elongate portion of the penetrating member. With any of the above embodiments, the cavity may be on the bottom or the top of the cartridge, with the gripper on the other side. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge may be in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member.

The penetrating member may have a diameter and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. In some embodiments, one pin may be configured to contact more than one electrode (such as a U-shaped pin that contacts both the counter and reference electrodes). The driver may use a through hole or other opening to engage a proximal end of a penetrating member to actuate the penetrating member along a path into and out of the tissue. It should be understood that any of the inventions herein may be used in conjunction with devices disclosed in U.S. Patent Applications Attorney Docket No. 38187-2551, 38187-2608, and 38187-2662. The present application is related U.S. Provisional Application Ser. No. 60/533,980 (Attorney Docket No. 38187-2726), U.S. Provisional Application Ser. No. 60/534,154 (Attorney Docket No. 38187-2728), and U.S. Provisional Application Ser. No. 60/533,996 (Attorney Docket No. 38187-2724).

The publications discussed or cited herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed. All publications, patents, and patent applications mentioned herein are incorporated herein by

reference to disclose and describe the structures and/or methods in connection with which the publications are cited.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either both of those included limits are also included in the invention.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

- 1 1. A body fluid sampling device for use on a patient, the device
2 comprising:
3 a support structure;
4 a sensory material on a first side of the support structure; and
5 at least one conductor pin.
- 1 2. A body fluid sampling device comprising:
2 a support structure;
3 a sensory material on a first side of said support structure; and
4 at least one conductor pin positioned to pierce into the sensory material to
5 create an electrical connection;
6 wherein said sensory material is sized to prevent said conductor pins from
7 piercing entirely through the material.
- 1 3. The device of claim 1 further comprising a radial cartridge, said
2 support structure coupled to said radial cartridge.
- 1 4. The device of claim 1 further comprising a radial cartridge
2 containing a plurality of penetrating members therein, said support structure coupled to
3 said radial cartridge.
- 1 5. The device of claim 1 further comprising a plurality of electrodes
2 each having said sensory material.
- 1 6. The device of claim 1 wherein the sensory material is configured to
2 measure analyte levels in fluid coming in contact with the sensory material.
- 1 7. The device of claim 1 wherein the sensory material is reactive to
2 glucose and is used to measure glucose levels in fluid coming in contact with the sensory
3 material.
- 1 8. The device of claim 1 wherein the sensory material is pliable
2 consistency that allows a conductor pin to pierce into it.

1 9. A method for use on a patient, the method comprising:
2 providing a sampling device having a cartridge in a housing, a plurality of
3 penetrating member in said cartridge; a plurality of analyte detecting members mounted
4 on said cartridge; and a plurality of pins mounted on said housing,
5 moving the pins and cartridge relative to one another,
6 piercing the analyte detecting members on the cartridge with the pins
7 movable relative to the housing to create a good electrical contact;
8 reading analyte measurements of fluid in contact with the analyte detecting
9 members.

1 10. The method of claim 9 wherein the analyte detecting members are
2 made of a material sufficiently pliable to be penetrated by the pins.

1 11. The method of claim 9 wherein a wicking member is coupled to
2 each of said analyte detecting member and positioned to extend over at least a portion of a
3 penetrating member exit chamber on said cartridge.

1 12. The method of claim 9 further comprising launching a penetrating
2 member in the cartridge through a wicking member mounted to receive fluid express
3 from a wound created on the patient.

1 13. The method of claim 9 further comprising removing the pins from
2 the analyte detecting members.

1 14. The method of claim 9 further comprising removing the pins from
2 the analyte detecting members and rotating the cartridge to bring an unused analyte
3 detecting member into an active position.

1 15. The method of claim 9 using three pins, where two of the three pins
2 are in electrical communication.

1 16. A body fluid sampling system for measuring analyte levels in the
2 body fluid, said system comprising:
3 a housing;
4 a cartridge in said housing;
5 a plurality of penetrating member in said cartridge;

6 a plurality of analyte detecting members mounted on said cartridge; and
7 a plurality of pins mounted on said housing, said pins and cartridge
8 movable relative to one another, said pins movable relative to the housing to pierce the
9 analyte detecting members on the cartridge to create a good electrical contact.

1 17. The system of claim 16 wherein a wicking member is coupled to
2 each of said analyte detecting member and positioned to extend over at least a portion of a
3 penetrating member exit chamber on said cartridge.

1 18. The system of claim 16 wherein the cartridge includes a plurality
2 of openings allowing the pins to engage an underside of the analyte detecting member.

1 19. The system of claim 16 wherein the pins are mounted on a movable
2 chassis that moves to engage the cartridge in a first position, and disengages from the
3 cartridge in a second position.

1 20. The system of claim 16 wherein the pins are mounted on the
2 housing and may repeatably pierce the cartridge to make the electrical connection for
3 each glucose measuring event.

1 21. The system of claim 16 wherein the pins are insulated on a lower
2 portion to prevent cross-talk.

1 22. The system of claim 16 wherein the analyte detecting member is
2 about 700 microns thick.

1 23. The system of claim 16 wherein the analyte detecting member is at
2 least about 500 microns thick.

1 24. The system of claim 16 wherein the analyte detecting member is at
2 least about 300 microns thick.

1 25. A device comprising:
2 a housing;
3 a cartridge in said housing;
4 at least one penetrating member in said cartridge;
5 at least one analyte detecting members mounted on said cartridge; and

6 at least one pin, wherein said pin and cartridge movable relative to one
7 another, the pin movable relative to the housing to pierce the analyte detecting members
8 on the cartridge to create a good electrical contact.

1 26. An actuation device comprising:
2 a combined lancing and blood sample analysis device in a single
3 disposable cartridge, said cartridge does not have conductive leads.

1 27. An actuation device comprising:
2 a combined lancing and blood sample analysis device in a single
3 disposable cartridge, said cartridge having a plurality of analyte detecting members
4 without conductive leads on the cartridge leading to a contact pad.

1 28. A body fluid sampling device comprising: [2724]
2 a support structure;
3 a sensory material on a first side of said support structure;
4 a conductor material on a second side of said support structure; and
5 at least one via hole defined by said support structure, said via hole
6 allowing said conductor material to contact said sensory material, said via hole sized to
7 allow some material to reach the other side of the substrate.

1 29. The device of claim 28 further comprising a radial cartridge, said
2 support structure coupled to said radial cartridge.

1 30. The device of claim 28 further comprising a plurality of electrodes
2 each having said sensory material.

1 31. The device of claim 28 further comprising a plurality of via holes
2 in said support structure, wherein each is sized to allow some material to reach the
3 other side of the substrate.

1 32. The device of claim 28 further comprising a plurality of via holes
2 in said support structure arranged in a configuration selected from one of the following:
3 circular, oval, or rectangular.

1 33. A device comprising:
2 a support structure;

3 a sensory material;
4 a conductor material; and
5 at least one via hole defined by said support structure.

1 34. A method comprising:
2 providing a support structure;
3 forming a plurality of miniature via holes in said support structure;
4 depositing sensory material on one side of said support structure; and
5 depositing conductor material on another side of said support structure,
6 said conductor material and sensory material in contact with one another.

1 35. The method of claim 34 further comprising coupling said support
2 structure to one side of a radial cartridge.

1 36. The method of claim 34 further comprising coupling said support
2 structure to one side of a radial cartridge and applying a sterility barrier around the entire
3 cartridge.

1 37. The method of claim 34 further comprising coupling said support
2 structure to one side of a radial cartridge and mounting a plurality of penetrating members
3 on the cartridge.

1 38. A device for use with a metering device for measuring analyte
2 levels, said device comprising:
3 a sensing disc;
4 a connector disc;
5 a plurality of analyte detecting members mounted on said sensing disc; and
6 a plurality of contact pads on the connector disc forming a lap joint with
7 the sensing disc, wherein the analyte detecting members face upward and the contact pads
8 of the connector disc face downward.

1 39. The device of claim 38 wherein said cartridge includes a plurality
2 of penetrating members.

1 40. The device of claim 38 wherein said cartridge sensing disc and
2 connector disc are joined by an overlapping joint.

1 41. The device of claim 38 wherein said cartridge does not include any
2 penetrating members.

1 42. The device of claim 38 wherein said cartridge uses analyte
2 detecting member of sufficient softness to be pierced by at least one connector pin.

1 43. The device of claim 38 wherein said cartridge further comprises a
2 wicking member and capillary structure, wherein the capillary structure is positioned to
3 draw fluid to the analyte detecting member.

1 44. The device of claim 38 wherein said cartridge has a radial disc
2 shape.

1 45. A device comprising:
2 a sensing disc;
3 a connector disc;
4 at least one analyte detecting member mounted on said sensing disc; and
5 at least one contact pad on the connector disc forming a lap joint with the
6 sensing disc.

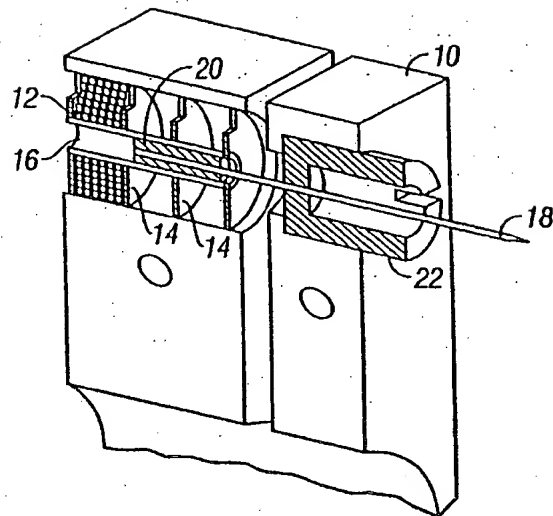


FIG. 1

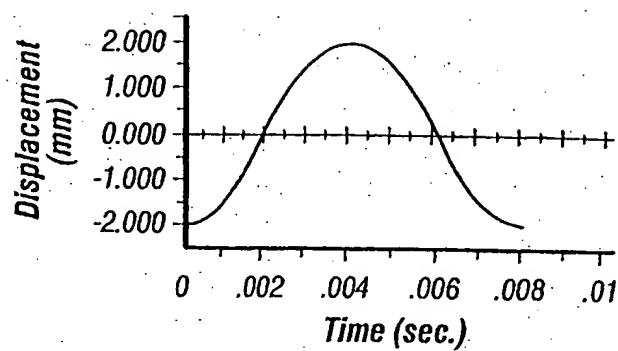


FIG. 2A

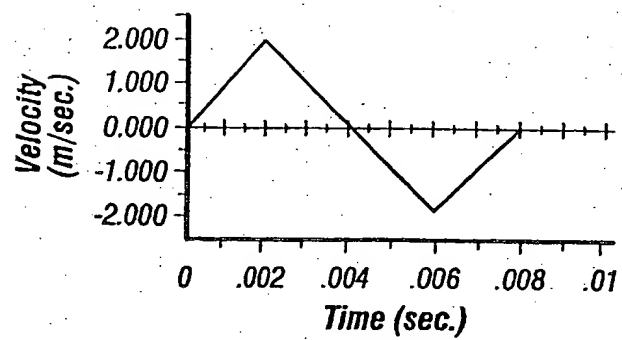


FIG. 2B

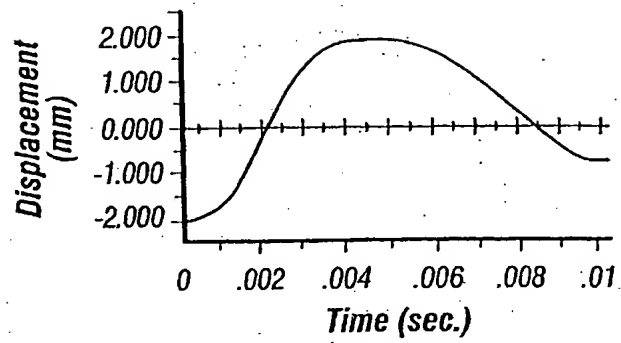


FIG. 2C

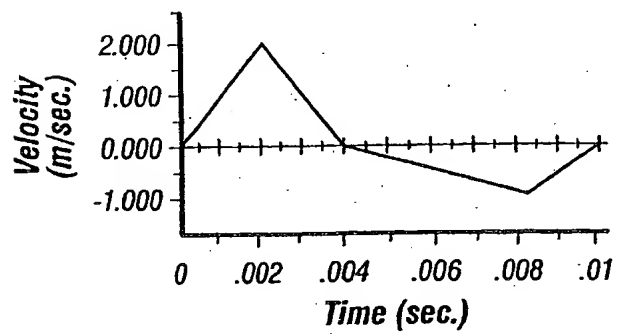


FIG. 2D

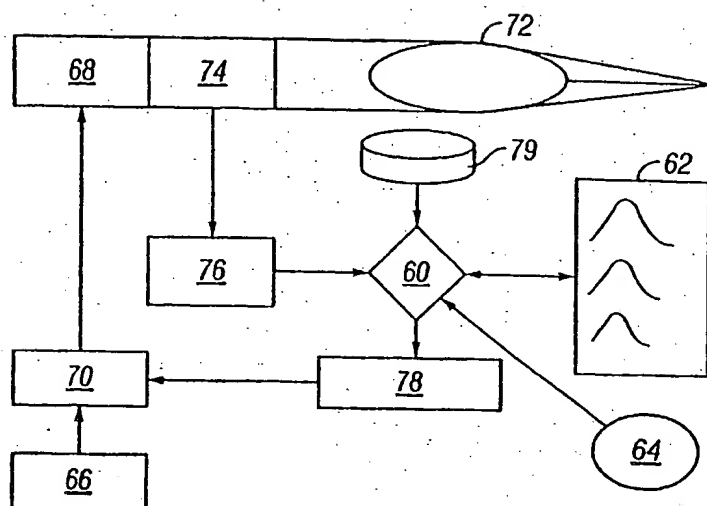


FIG. 3

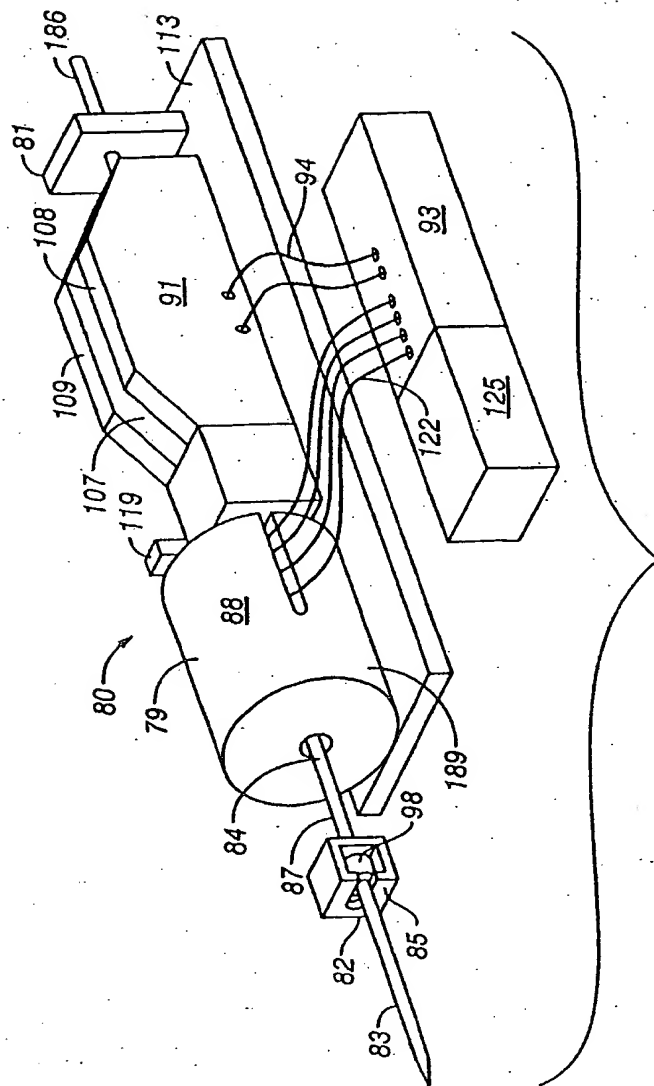


FIG. 4

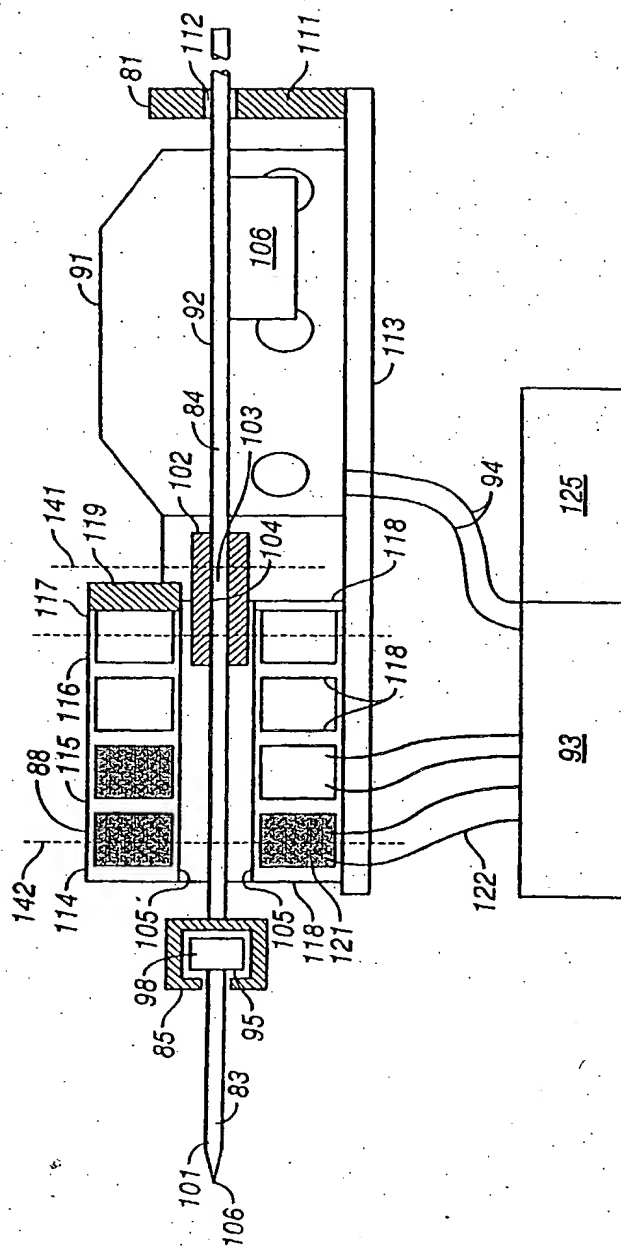


FIG. 5

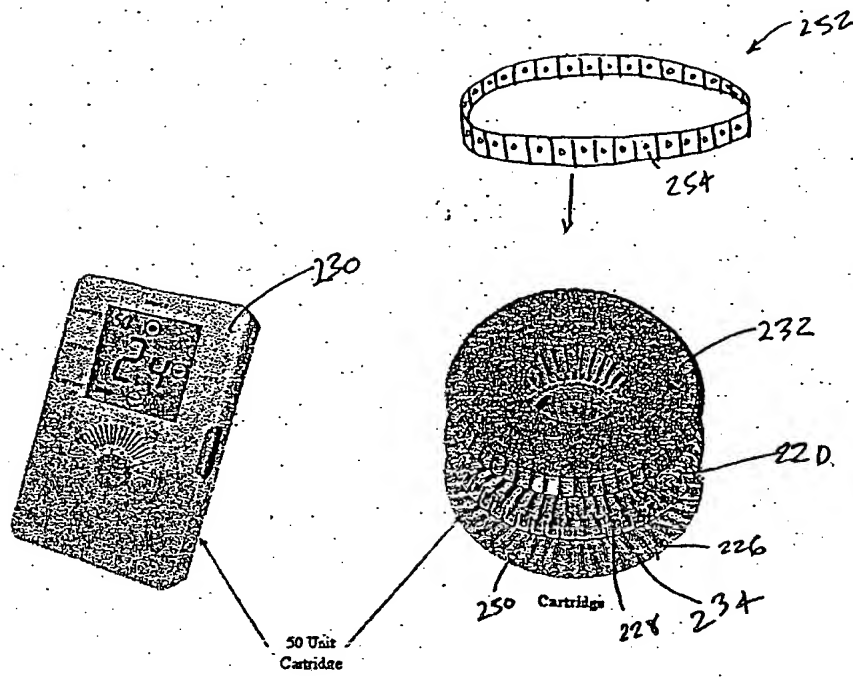


FIG. 6A

FIG. 6B

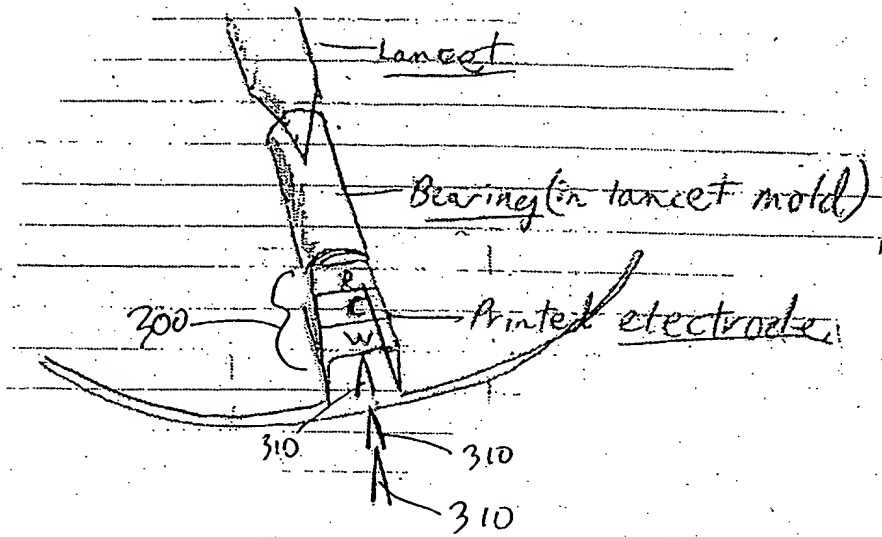


FIG-7A

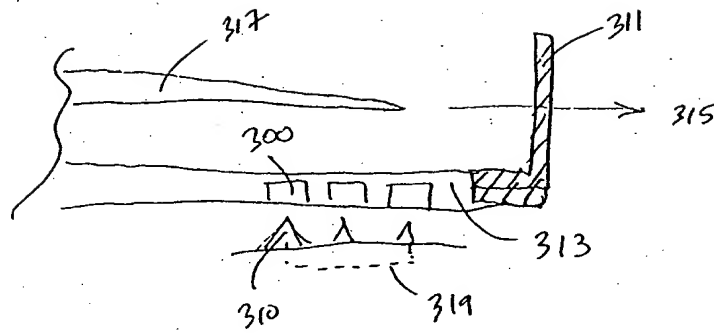


FIG. 7B

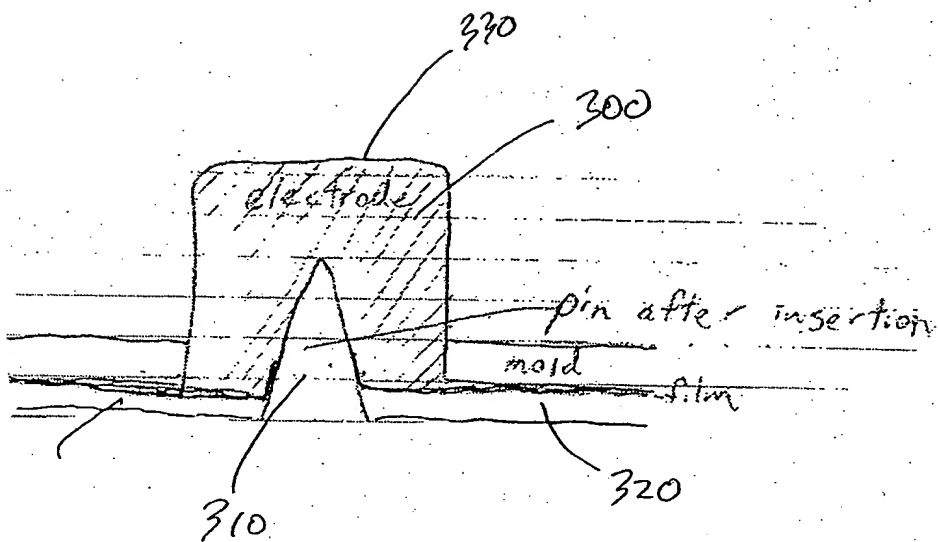


FIG-8

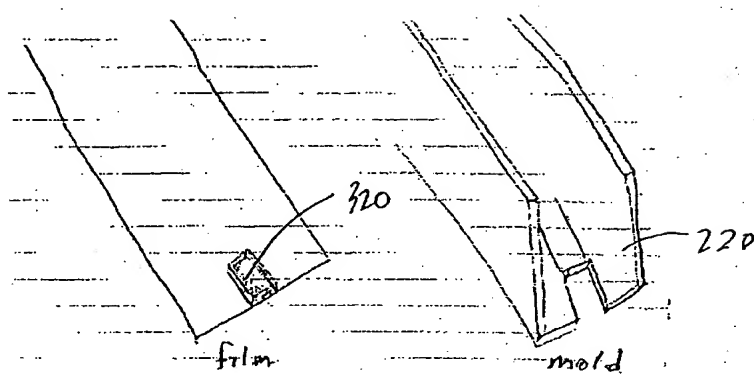


FIG. 9A

FIG. 9B

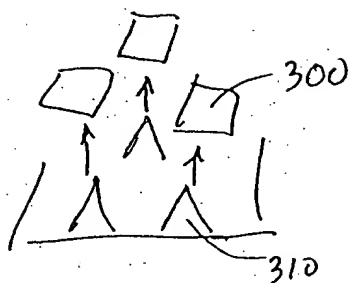


FIG-10A

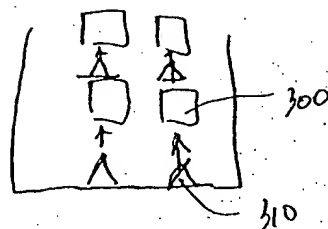


FIG-10B

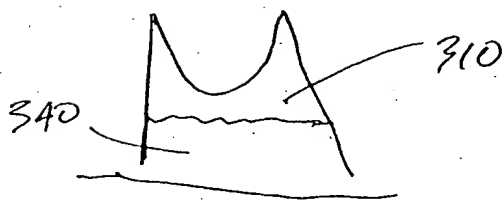
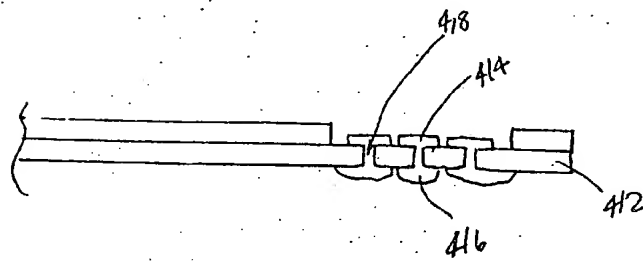
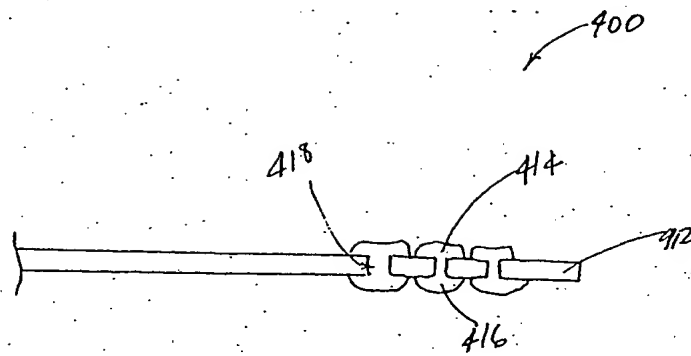


FIG-11A



FIG-11B



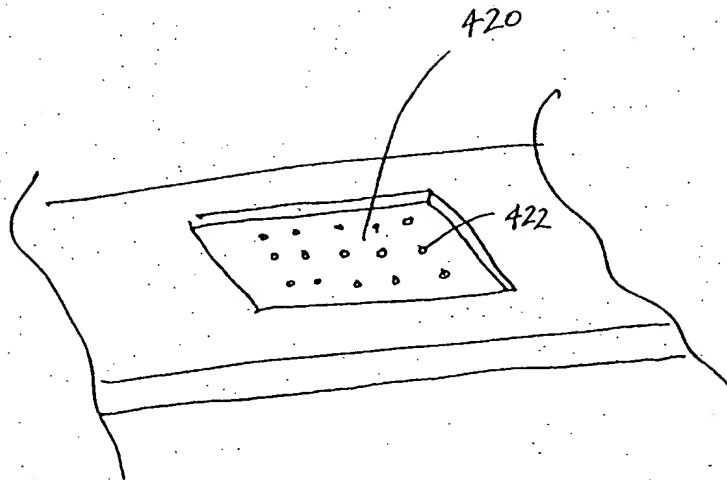


FIG. 14

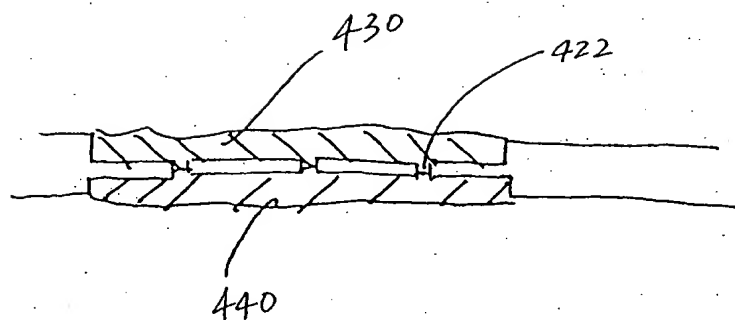


FIG-15

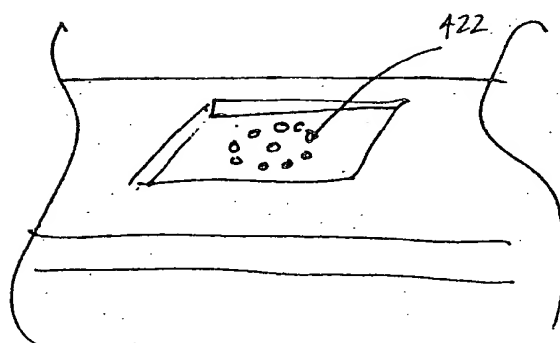


FIG-16

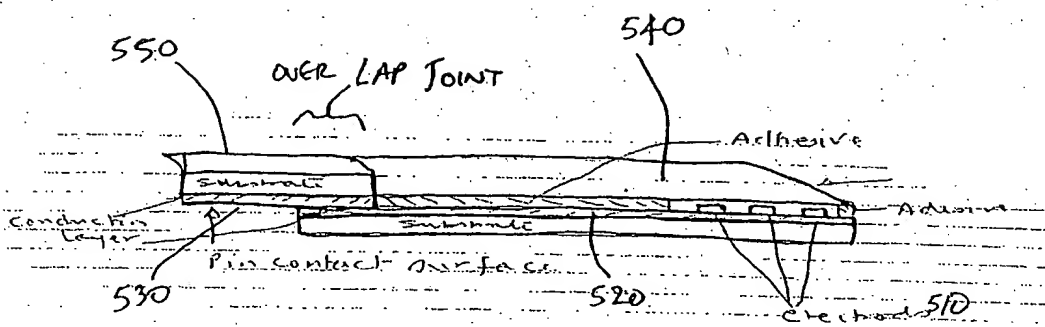


FIG-17

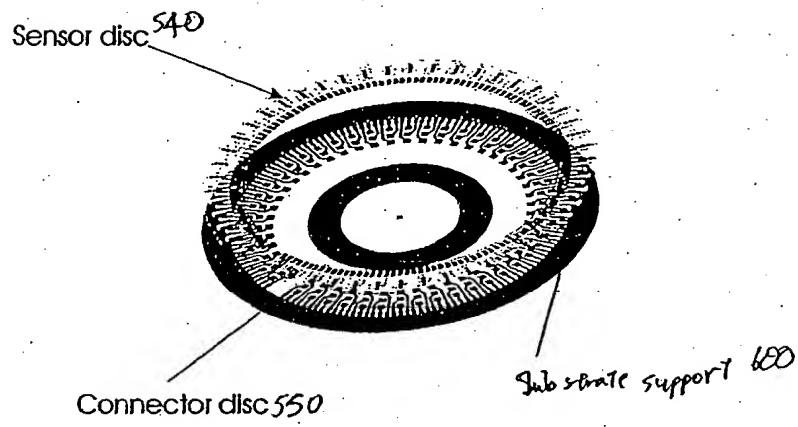
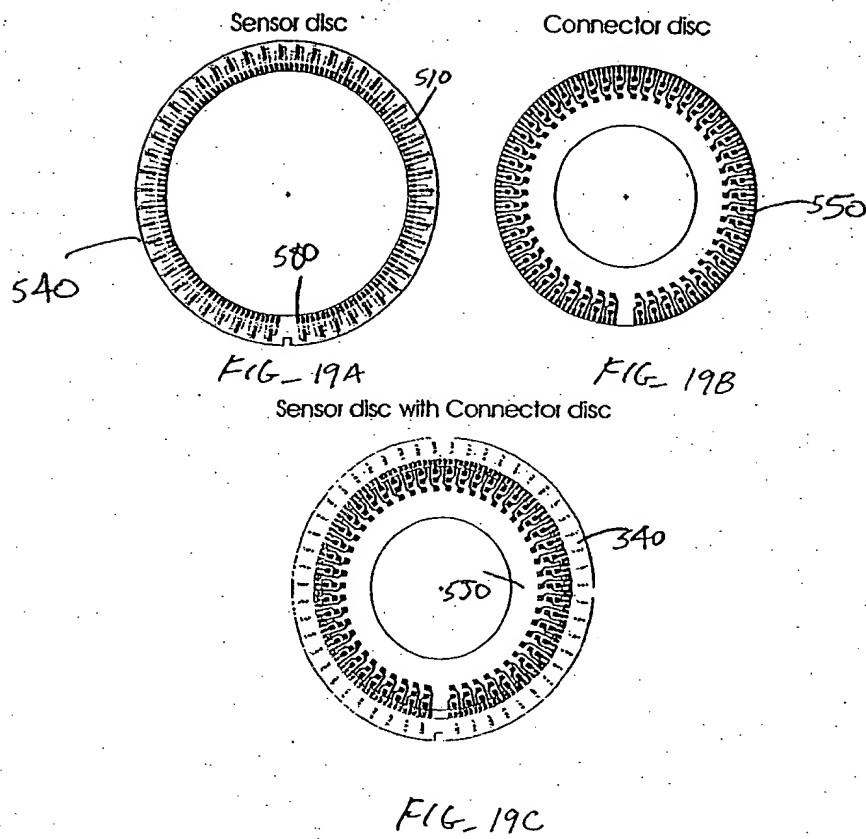


FIG. 18



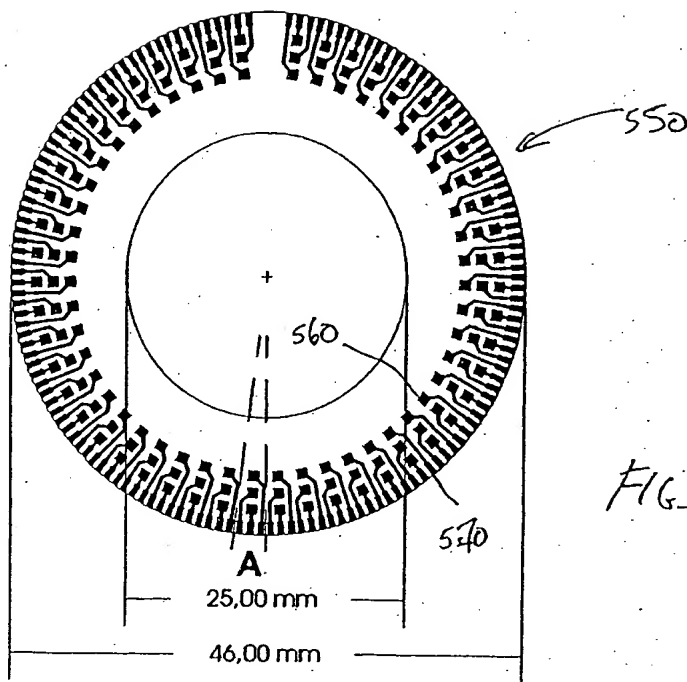


FIG 20

Detail: A

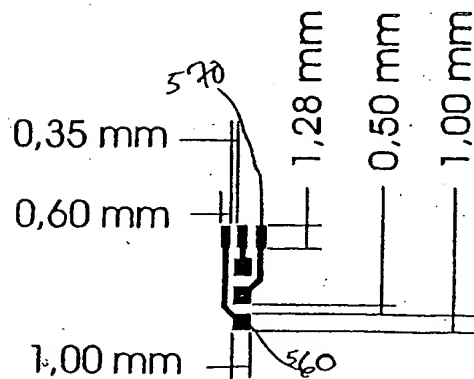


FIG 21

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